UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

UNITED STATES OF AMERICA, Plaintiff, v. TERUMO CARDIOVASCULAR SYSTEMS CORPORATION, a corporation, MARK A. SUTTER, and MARK LINCOLN, individuals, Defendants.	)	Civil No. _____

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

JURISDICTION AND VENUE

1. This is a statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), 21 U.S.C. § 332(a), and the equitable authority of this Court, to enjoin Terumo Cardiovascular Systems Corporation ("TCVS"), Mark A. Sutter, and Mark Lincoln (collectively, "Defendants"), from the following unlawful conduct:

A. violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce articles of device, as defined by 21 U.S.C. § 321(h), that are (1) adulterated within the meaning of 21 U.S.C. § 351(h), in that the methods used in, and the facilities and controls used for, their manufacture, packing, storage, and installation are not in conformity with the current

good manufacturing practice ("CGMP") requirements, as set forth in 21 U.S.C. § 360j(f)(1) and the Quality System ("QS") regulation, 21 C.F.R. Part 820; and (2) misbranded within the meaning of 21 U.S.C. § 352(t)(2), in that Defendants fail to furnish information or material respecting the company's devices, as set forth in 21 U.S.C. § 360i and the medical device reporting ("MDR") regulation, 21 C.F.R. Part 803;

B. violating 21 U.S.C. § 331(k) by doing acts that result in the adulteration, within the meaning of 21 U.S.C. § 351(h), of articles of device, as defined by 21 U.S.C. § 321(h), while such devices are held for sale after the shipment of one or more of their components in interstate commerce; and

C. violating 21 U.S.C. § 331(e) by failing to maintain and submit reports respecting the company's devices, as required by 21 U.S.C. § 360i and 21 C.F.R. Part 803.

2. This Court has jurisdiction over this action and all Defendants under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c).

BACKGROUND

Devices Used in Cardiopulmonary Bypass Procedures

4. Thousands of cardiopulmonary bypass ("CPB") procedures are performed every day in the United States. These procedures include, for example, coronary artery bypass surgery, cardiac valve repair or replacement, repair or palliation of congenital heart defects, and heart transplantation. Two medical technologies have made such surgeries possible: (a) the cardiopulmonary bypass

machine (also known as “heart-lung machine” or “perfusion system”), which takes over the functions of the heart and lungs during surgery; and (b) body-cooling techniques, which slow the patient’s metabolic rate and allow more time for surgery without causing brain damage. A heart-lung machine keeps oxygen-rich blood flowing throughout the body after the patient’s heart has been carefully stopped. In a process called “perfusion,” the heart-lung machine receives the patient’s blood, removes the carbon dioxide and other waste products, adds oxygen, warms (or cools) the blood and then pumps it back through the body. Cooling the blood lowers body temperature, which protects the body’s organs while the heart-lung machine is in use. After the surgery is completed, the heart is restarted and the heart-lung machine is stopped and disconnected from the patient.

5. A perfusion system consists of several component devices that provide critical, complementary functions during CPB procedures. These devices include, but are not limited to, the oxygenator, the air bubble detector, the blood-parameter monitor, the temperature management system, the arterial and venous blood pumps, and various cannulae and catheters. Because these devices work together to replace (substitute) the functions of the heart and lungs, maintaining the circulation of blood and the oxygen content of the body during CPB surgeries, the devices collectively perform vital, life-sustaining roles during CPB procedures.

6. The heart-lung machines are used to perform CPB procedures on individuals of all ages. However, the populations at greatest risk and most vulnerable when a heart-lung machine (or one of its components) fails are neonates

and infants with complex congenital abnormalities, the elderly, and immuno-compromised patients.

Brief Description of FDA Regulation of Medical Devices

7. Devices, as defined in 21 U.S.C. § 321(h), are subject to regulation by the United States Food and Drug Administration ("FDA"). Life-supporting devices such as heart-lung machines must be manufactured and marketed according to both general and special mandatory controls to provide reasonable assurance of their safety and effectiveness. See 21 U.S.C. § 360c(a)(1). These controls include the QS regulation, 21 C.F.R. Part 820, promulgated pursuant to 21 U.S.C. § 360j(f), which governs the manufacture, packing, storage, and installation of devices to ensure compliance with the CGMP requirements.

8. The QS system is designed to be prophylactic. It includes four subsystems: (a) management controls, (b) corrective and preventive actions ("CAPA"), (c) production and process controls, and (d) design controls.

9. In addition to the QS regulation, devices such as heart-lung machines also are subject to strict post-marketing, MDR requirements, as set forth in 21 C.F.R. Part 803.

Defendants and Their Business

10. Defendant TCVS is a corporation incorporated under the laws of the State of Delaware. TCVS manufactures and markets various devices used in cardiac and vascular surgery including, but not limited to, CPB devices (heart-lung devices), air bubble detectors ("ABDs"), level monitors, flow monitors, pressure monitors, temperature monitors, gas monitors, central control monitors, roller pumps,

centrifugal control units, centrifugal drive motors, electronic oxygen blenders and analyzers, blood-parameter monitors and calibrators, venous occluders, cables, stainless steel connectors, electronic patient gas system oxygen sensors, intraoperative monitoring systems, reducers, cannula prime lines, cooling and heating devices, data management systems, hematocrit/oxygen saturation monitoring systems, cannulae, catheters, and accessories for disposable devices, including, but not limited to, accessories for myocardial protection products and bubble traps. TCVS has its headquarters and does business at 6200 Jackson Road, Ann Arbor, Michigan, within the jurisdiction of this Court.

11. Defendant Mark A. Sutter, an individual, is TCVS's President and Chief Executive Officer. He has authority over all of the company's operations including, but not limited to, the manufacture, packing, storage, and installation of TCVS's devices. He is involved in the day-to-day activities at TCVS. Mr. Sutter performs his duties at 6200 Jackson Road, Ann Arbor, Michigan, within the jurisdiction of this Court.

12. Defendant Mark Lincoln, an individual, is TCVS's Vice President of Quality Assurance and Operations, a position he assumed on September 17, 2010. He is responsible for compliance with the QS regulation at all TCVS facilities. He performs his duties at 6200 Jackson Road, Ann Arbor, Michigan, within the jurisdiction of this Court.

13. Defendants have been and are now engaged in manufacturing, packing, storing, installing, and introducing into interstate commerce various products that are articles of device within the meaning of 21 U.S.C. § 321(h).

14. Defendants regularly manufacture devices from components they receive in interstate commerce and introduce finished devices into interstate commerce for shipment outside the State of Michigan.

DEFENDANTS' CONDUCT

Defendants Adulterate Devices by Violating the QS Regulation

15. FDA inspected Defendants' Ann Arbor, Michigan facility from January 4 to March 29, 2010. This inspection revealed that the methods Defendants use in, and the facilities and controls they use for, the manufacture, packing, storage, and installation of their devices are not in compliance with the QS regulation, 21 C.F.R. Part 820.

16. During the January-March 2010 inspection, FDA investigators found that Defendants' overall QS system has deficiencies in the following subsystems: CAPA, production and process controls, and design controls. The FDA investigators observed, among others, the following deficiencies in TCVS's QS subsystems:

A. Defendants failed to determine whether TCVS's device caused or contributed to a patient's death, after Defendants received a complaint in which a hospital-customer stated that a patient died after TCVS's cannula was removed from the patient and a blood clot was found entangled in the diffuser tip of the cannula.

B. Defendants failed to ensure that the sole supplier of TCVS's ABD Ultrasonic Air Sensors ("UAS") provide devices that conform to required specifications.

C. Defendants failed to fully investigate the cause for many inaccuracies in potassium measurements associated with TCVS's blood-parameter monitors used in CPB procedures.

D. Defendants failed to fully investigate the cause of many complaints received between March 2008 and November 2009 that described malfunctions associated with TCVS's ABDs, which led to false air emboli detection alarms, inability to reset ABD systems, and stoppage of arterial pumps during bypass surgery.

E. Defendants failed to implement actions to address various workmanship problems (e.g., flux contamination, incorrect parts, solder problems, and corrosion) associated with a supplier's printed circuit board ("PCBs"), which are used in components that comprise the TCVS heart-lung machine, even though Defendants have been aware of these problems for years.

F. Defendants failed to fully investigate the cause(s) associated with the mixing-valve malfunctions in TCVS's HX2 Temperature Management System and to apply any corrective action taken with respect to that system to distributed devices.

G. Defendants failed to correct the software of the roller pumps, which are used to circulate blood during CPB procedures, even though Defendants knew that the software contained errors that may lead to pump stoppages and malfunctions.

H. Defendants failed to fully validate the process used to coat various models of TCVS's disposable single-use cannulae and catheters, which coating is intended to reduce the risk of blood clots during surgery.

Defendants Misbrand Devices by Violating the MDR Regulation

17. FDA's January-March 2010 inspection of TCVS further revealed that, in addition to their failure to comply with the QS regulation, Defendants failed to comply with the MDR regulation, 21 C.F.R. Part 803, promulgated pursuant to 21 U.S.C. § 360i. During the inspection, the FDA investigators documented, among others, the following failures to comply with the MDR requirements:

A. TCVS learned that its Soft Flow Arterial Cannula was used during an operation in which the patient died and that a blood clot was entangled in the diffuser tip of the cannula upon removal from the patient. Yet TCVS failed to investigate further and report this incident to FDA.

B. TCVS's VirtuoSaph Endoscopic Vein Harvesting System was designed to allow surgeons to harvest leg veins through a small incision in the leg to minimize scarring, morbidity, and infection associated with traditional longitudinal ("open leg") incisions. TCVS received at least three complaints from hospitals that its VirtuoSaph devices malfunctioned, which forced the surgeons to undertake a more invasive procedure of cutting open the patients' legs to harvest the veins. Defendants failed to submit MDRs for these adverse events.

C. TCVS received a complaint that one of its blood pumps failed during bypass surgery, but TCVS reported in an MDR to FDA that the failure occurred during routine testing. Moreover, in that same report, TCVS failed to describe the event or problem, its nature, and how TCVS's device was involved.

D. Hospitals filed many complaints with TCVS describing malfunctions of TCVS's blood-parameter monitors that caused inaccurate potassium measurements ("potassium drifts") during CPB surgeries, which could pose severe health risks to patients. Defendants failed to report these incidents to FDA.

18. Through their conduct, which includes but is not limited to the conduct described in Paragraph 17 above, Defendants cause their devices to be misbranded within the meaning of 21 U.S.C. § 352(t)(2).

Defendants Violate 21 U.S.C. §§ 331(a), (e) and (k)

19. As a result of the unlawful conduct set forth in Paragraphs 15-18 above, Defendants have been and are violating 21 U.S.C. § 331(a), by introducing and delivering for introduction, and causing the introduction or delivery for introduction, into interstate commerce articles of device, as defined by 21 U.S.C. § 321(h), that are adulterated and misbranded with the meaning of 21 U.S.C. §§ 351(h) and 352(t)(2), respectively.

20. As a result of the unlawful conduct set forth in paragraphs 15-16 above, Defendants further have been and are violating 21 U.S.C. § 331(k), by doing an act that results in the adulteration of articles of device, as defined by 21 U.S.C. § 321(h), while such articles are held for sale after the shipment of one or more of their components in interstate commerce.

21. As a result of the unlawful conduct set forth in Paragraphs 17-18, Defendants further have been and are violating 21 U.S.C. § 331(e), by failing to maintain and submit reports respecting the firm's devices, as required by 21 U.S.C. § 360i.

PRIOR NOTICE

22. FDA investigators observed that many of Defendants' QS and MDR violations identified during the January-March 2010 inspection were the same as, or similar to, prior violations observed by FDA and found in previous FDA inspections in 2008, 2005, and 2004. At the close of each FDA inspection of Defendants' Ann Arbor, Michigan facility in 2010, 2008, 2005, and 2004, FDA investigators issued a detailed List of Inspectional Observations ("Form FDA-483") to Defendants and discussed the violations with them. In addition, although a warning is not required for an FDA enforcement action, FDA issued Warning Letters to the company after the 2005 and 2004 inspections and, following the 2008 inspection, FDA held a regulatory meeting with the company.

PRAYER FOR RELIEF

WHEREFORE, the United States of America prays:

I. That Defendants Terumo Cardiovascular Systems Corporation, Mark A. Sutter (TCVS's President and Chief Executive Officer), and Mark Lincoln (TCVS's Vice President of Quality Assurance and Operations), and each and all of their directors, officers, agents, representatives, employees, successors, assigns, and attorneys, and any and all persons in active concert or participation with any of them, be permanently enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing the following acts:

A. Introducing or causing to be introduced into interstate commerce, and delivering and causing to be delivered for introduction into interstate commerce, any article of device, as defined by 21 U.S.C. § 321(h);

B. Manufacturing, packing, storing, installing, and distributing any article of device while such article is held for sale after shipment of one or more of its components in interstate commerce unless and until Defendants satisfy FDA that (1) the methods, facilities, and controls used for the manufacture, packing, storage, and installation of articles of device are established, operated, and administered in conformity with the QS regulation, as set forth in 21 C.F.R. Part 820; and (2) Defendants have an adequate and effective process for submitting information or material respecting their devices, as set forth in 21 C.F.R. Part 803; and

C. Failing to maintain and submit reports respecting Defendants' devices, as required by 21 U.S.C. § 360i and 21 C.F.R. Part 803.

II. That Defendants and each and all of their directors, officers, agents, representatives, employees, successors, assigns, and attorneys, and any and all persons in active concert or participation with any of them, be perpetually restrained and enjoined pursuant to 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts with respect to devices:

A. Violating 21 U.S.C. § 331(a), by introducing or causing to be introduced into interstate commerce, and delivering and causing to be delivered for introduction into interstate commerce, articles of device, as defined by 21 U.S.C. § 321(h), that are adulterated, within the meaning of 21 U.S.C. § 351(h), and misbranded, within the meaning of 21 U.S.C. § 352(t)(2);

B. Violating 21 U.S.C. § 331(k), by doing or causing any act that results in the adulteration, within the meaning of 21 U.S.C. § 351(h), of articles of device, as defined by 21 U.S.C. § 321(h), while such devices are held for sale after the shipment of one or more of their components in interstate commerce; and

C. Violating 21 U.S.C. § 331(e), by failing to maintain and submit reports respecting the firm's devices, as required by 21 U.S.C. § 360i.

III. That the Court award the United States costs and other such equitable relief, including equitable monetary relief, as the Court deems just and proper.

DATED this 23rd day of March, 2011.

Respectfully submitted,

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